

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PLUMBERS & PIPEFITTERS LOCAL 178 HEALTH
& WELFARE TRUST FUND, on Behalf of Itself and
All Others Similarly Situated,

Plaintiff,

V.

TEVA PHARMACEUTICALS USA, INC.; TEVA
PHARMACEUTICAL INDUSTRIES LIMITED;
BARR PHARMACEUTICALS INC.; BARR
LABORATORIES INC.; DURAMED
PHARMACEUTICALS INC.; DURAMED
PHARMACEUTICALS SALES CORP.;
BOEHRINGER INGELHEIM PHARMA GMBH &
CO. KG.; BOEHRINGER INGELHEIM
INTERNATIONAL GMBH; and BOEHRINGER
INGELHEIM PHARMACEUTICALS, INC.,

Defendants.

Case No.

CLASS ACTION

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Plumbers & Pipefitter Local 178 Health & Welfare Trust Fund (“Plaintiff” or “Local 178”), on behalf of itself and all others similarly situated, files this Class Action Complaint (“Complaint”) against Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Limited (collectively “Teva”), Barr Pharmaceuticals Inc., Barr Laboratories, Inc. (collectively “Barr”), Duramed Pharmaceuticals Inc., Duramed Pharmaceuticals Sales Corp. (collectively “Duramed”), Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively “Boehringer”), as follows:

NATURE OF ACTION

1. Plaintiff brings this antitrust action on behalf of a proposed class of end-payors who indirectly purchased, reimbursed, or otherwise paid for a drug called Aggrenox, which is a combined aspirin and extended-release dipyridamole treatment to lower the risk of stroke in people who have had a transient ischemic attack or stroke due to a blood clot. Defendants have engaged in anticompetitive conduct that has prevented a less expensive generic equivalent of Aggrenox from entering the market. Defendants' conduct violates federal and state law. Plaintiff seeks damages, an order enjoining defendants' anticompetitive conduct, and other relief.

2. Boehringer started selling Aggrenox in December 1999. Aggrenox has been a commercial success and steady source of profit for Boehringer, with sales reaching \$366 million in 2008.

3. In January 2007 Barr sought regulatory approval to market a generic version of Aggrenox. To delay the substantial loss of profits it would suffer from competing generic versions of Aggrenox, in August 2008 Boehringer entered into an exclusion payment agreement (commonly known as a "pay-for-delay" agreement) with Barr. Under this agreement, Boehringer agreed to pay Barr in exchange for Barr's commitment to postpone marketing its generic version of Aggrenox until July 1, 2015. Boehringer's payment took the form of: (a) compensation provided under a co-promotion agreement – an estimated \$120 million in one-time and yearly royalty payments – that far exceeds the value of the services provided by Barr; and (b) an agreement to not compete against Barr with Boehringer's own authorized generic Aggrenox product.

4. But for the pay-for-delay agreement, less expensive generic equivalents of Aggrenox would have been available much sooner than July 2015. Because of the pay-for-delay agreement, plaintiff has paid more for Aggrenox than it would have absent defendants' anti-competitive

conduct. Defendants have shared in the illicit profits that have resulted from the artificially inflated prices plaintiff paid for Aggrenox.

5. Plaintiff brings this action on its own behalf and on behalf of a proposed class of consumers and third-party payors who purchased or paid for Aggrenox, other than for resale, since August 14, 2009. Plaintiff seeks a judgment declaring that the exclusion payment agreement is unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff also seeks an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, because, unless enjoined, the defendants' unlawful conduct will continue unchecked and plaintiff will continue to suffer financial harm as a result of defendants' antitrust violations. Plaintiff also asserts claims for compensatory and treble damages and equitable relief for continuing violations of state antitrust and unjust enrichment laws.

PARTIES

A. Plaintiff

6. Plaintiff Plumbers & Pipefitter Local 178 Health & Welfare Trust Fund ("Local 178" or "Plaintiff") is located in Springfield, Missouri. Local 178 purchased Aggrenox indirectly from Boehringer during the Class Period as defined below, and was injured by the illegal conduct described herein.

B. Defendants

7. Defendant Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceuticals Industries Limited, is a Delaware corporation with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania. It manufactures and distributes generic drugs for sale throughout the United States at the direction, under the control, and for the direct benefit of its parent company.

8. Defendant Teva Pharmaceuticals Industries Limited is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva is a leading manufacturer of generic drugs, and is one of the largest sellers of generic drugs in the United States. Teva purchased Barr Pharmaceuticals Inc. on December 23, 2008.

9. Defendant Barr Pharmaceuticals Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey.

10. Defendant Barr Laboratories, Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey.

11. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva.

12. Defendant Duramed Pharmaceuticals Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In December 2008, when Teva and is now known as Teva Women's Health Inc.

13. Defendant Duramed Pharmaceuticals Sales Corp. is a corporation organized under the laws of the state of Delaware, with a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. It was a subsidiary of Barr until December 2008, when it became a subsidiary of Teva.

14. Defendant Boehringer Ingelheim Pharma GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany, with its principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

15. Defendant Boehringer Ingelheim International GmbH is a limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

16. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut.

17. All of the defendants' actions described in this complaint are part of, and were in furtherance of, the illegal restraint of trade alleged herein, and were authorized, ordered, and performed by the defendants' various officer, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs, within the course and scope of their duties and employment, and with the actual, apparent or ostensible authority of the defendants.

JURISDICTION AND VENUE

18. This Court also jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that the Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1-2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

19. Alternatively, this Court has jurisdiction pursuant to 28 U.S.C. §1332(d) and the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1711, et seq., which vests original jurisdiction in the district courts of the United States for any multi-state class action where the aggregate amount in controversy exceeds five million dollars and where the citizenship of any member of the class of plaintiffs is different from that of any defendant. The five million dollar amount-in-controversy and diverse-citizenship requirements of CAFA are satisfied in this case.

20. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391, because Defendants transact business in this District. A substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

REGULATORY BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

21. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's product choice and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

22. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Aggrenox, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

23. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products.

These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

24. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The market imperfections and marketing practices described above allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. Generic Versions of Brand Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand Versions

25. Manufacturers of generic drugs typically price their versions of brand drugs significantly below the brand price. These price differentials prompt pharmacists to liberally and substantially substitute generic versions for the brand counterparts whenever generics are available and substitution is legally permissible. In particular, generic drugs that are pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to their brand name counterparts are given an “AB” rating by the FDA. Pharmacists substitute a less-expensive AB-rated generic product for the corresponding brand product unless the doctor has indicated that the prescription for the brand product must be “dispensed as written” or the patient objects. As more

generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generics accelerates.

26. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written.

27. Many third-party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. In addition, many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a rapid and significant reduction of the branded drug's unit and dollar sales.

28. Once a generic equivalent enters the market, the generic quickly captures sales of the brand drug, often capturing 80% or more of unit sales within the first six months. Typically, about one year after market entry, the generic version often takes more than 90% of the brand's unit sales and sells for approximately 15% of the brand price.

29. Generic competition enables purchasers at all levels of the pharmaceutical supply chain, including all members of the proposed Class, to: (a) purchase generic versions of a drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price. Until a generic manufacturer enters the market, however, there is no bioequivalent generic drug to compete with the brand drug, and therefore the brand manufacturer can continue to profit from supracompetitive pricing, without losing its brand sales. Consequently, brand drug manufacturers have a strong

incentive to use various tactics, including those alleged above, to delay the introduction of generic competition into the market.

30. Brand manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

C. The Regulatory Structure for FDA Approval of Generics

31. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-392) ("FDCA"), manufacturers that create a new, pioneer drug must obtain the FDA's approval to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information regarding applicable patents.

32. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

33. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

34. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent and pharmaceutically equivalent to the brand-name drug.

35. As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman provided a number of benefits to brand-drug manufacturers. For example, Hatch-Waxman grants a 5-year period of exclusivity (regardless of any patent protection) to NDAs for products containing chemical entities never previously approved by FDA either alone or in combination. Hatch-Waxman also grants a 3-year period of exclusivity (regardless of any patent protection) for a drug product that contains an active ingredient that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application.

36. Hatch-Waxman also streamlined the process for a brand manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions, the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand drug for up to 30 months.

37. When the FDA approves a brand manufacturer's NDA, the FDA lists any compound patents which (according to the brand manufacturer) claim the approved drug, in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). In the case of method-of-use patents, the FDA lists in the Orange Book any patents that (according to the brand manufacturer) claim the drug for its approved method of use. Method-of-use patents are properly submitted to the FDA for Orange Book listing only if the manufacturer could reasonably assert a claim of patent infringement against a person who was not licensed by the owner to manufacture, use, or sell the drug. 21 U.S.C.A. § 355(b)(1). In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand manufacturer may list other

new patents in the Orange Book as related to the NDA, if the brand manufacturer similarly certified, inter alia, that the new patents claim either the approved drug (for compound patents) or that the patents claim the drug for approved methods of use (for method-of-use patents).

38. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand drug), a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

- a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
- b. that the patent for the brand drug has expired (a "Paragraph II certification");
- c. that the patent for the brand drug will expire on a particular date and the generic manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
- d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

39. If a generic manufacturer files only paragraph I, II, or III certifications, then it can take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

40. If a generic manufacturer files a Paragraph IV certification asserting that a patent listed in the Orange Book is invalid or will not be infringed, a brand manufacturer often has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug. The generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of

the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then in certain circumstances the FDA may not grant final approval of the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification, a brand manufacturer often may delay the FDA's approval of the generic drug and its entry into the market. During the pendency of an applicable 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay. The FDA does not grant tentative approvals when 30-month stays are inapplicable, however.

41. Congress also created incentives for generic manufacturers to seek approval of generic alternatives to branded drugs and challenge weak patents. Hatch-Waxman grants to the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification to at least one Orange Book-listed patent (a "first-filer"), a 180-day period of market exclusivity ("180-day exclusivity"), during which the first-filer enjoys temporary freedom from competition from other generic versions of the drug approved via ANDA. This 180-day exclusivity period (or any period during which there is only one generic version of a brand name drug on the market) is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. The entry of a second generic (or additional generics) can cut the original generic price by half or more. Selling six months' worth of a generic drug for a product such as Aggrenox, as the only generic on the market, can be worth hundreds of millions of dollars in profit.

D. Manufacturers' "Gaming" of the Regulatory Structure

1. Abuse of the 30-month Stay Provision

42. Brand manufacturers can "game the system" by listing patents in the Orange Book (even patents that are not eligible for listing) and then suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the patent is clearly invalid, or the generic's product is non-infringing) in order to obtain the automatic 30-month stay and delay final FDA approval of the ANDA for up to two and a half years. Brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition, rather than to enforce valid patents against infringing products. Generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in 73% of the cases studied.

2. Exclusion Payments and Bottlenecks

43. In order to delay the drastic loss of monopoly profits from their branded drugs, some unscrupulous brand manufacturers design schemes whereby they buy their way out of competition from generics and the chance that the brand patents might be invalidated or found not to be infringed. Brand manufacturers sometimes compensate the generic manufacturers to defer entering the market and to drop their challenges to the patents. Brand and generic manufacturers often try to disguise these payments, using various subterfuges as a way to try to escape liability under the antitrust laws.

44. Although these Exclusion Payment Agreements purport to settle patent infringement suits, in making a payment to the accused infringer, the patentee is using the strength of its wallet, as opposed to the strength of its patents, to obtain the agreement of the generic manufacturers to delay entry into the market and to avoid a court decision as to whether the patent is invalid or not infringed. The brand manufacturer effectively shares some of its monopoly profits with the generic

manufacturers as the quid pro quo for their agreement to delay competition. The brand and generic manufacturers split between themselves the savings that earlier generic entry would have brought to consumers.

45. Moreover, the first generic applicant can help the brand manufacturer “game the system” by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity “parking.” This tactic creates a “bottleneck” because later generic applicants cannot launch their generic versions of the product until the first generic applicant’s 180-day exclusivity has elapsed or is forfeited.

46. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) in order to make it more difficult for brand and generic manufacturers to conspire to delay the start of the first-filer’s 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. Under the “failure to market” provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity, at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that included a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

47. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic manufacturer filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in Paragraph IV litigation.

48. The brand manufacturer and first-filer frequently take various steps to fortify the bottleneck by making it less economically viable for subsequent filers to trigger the first-filer's exclusivity. For instance, Exclusion Payment Agreements often include "poison pill" provisions, which allow the first-filer to enter to enter the market before the later date otherwise agreed with the brand manufacturer, if a subsequent filer succeeds in entering the market before that later date. The co-conspirators disclose these terms publicly, thus broadcasting to subsequent filers that even if they incur the substantial expense involved in dislodging the bottleneck, they will be guaranteed to face competition from at least the first-filer, and likely others. By eliminating all possibility that subsequent filers will enjoy any period of de facto exclusivity, these poison pill provisions significantly reduce the value to subsequent filers of obtaining a court decision that would break the bottleneck. Thus, where a first-filer has "parked" its 180-day exclusivity and agreed to a poison pill

provision, subsequent filers have comparatively less to gain by obtaining a court decision of invalidity and/or non-infringement and are therefore willing to settle for much less time on the market than they otherwise would have.

3. No-Authorized-Generic Agreements

49. No-Authorized-Generic Agreements are Exclusion Payment Agreements, exploiting the 180 days of exclusivity given to the first filing generic. The 180-day marketing exclusivity to which first-filer generic may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an “authorized generic” is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturers’ subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer’s revenue, and substantially reduces drug prices for consumers.

50. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the “FTC Study”), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic’s revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

51. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiff and the Class benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

52. Given the significant negative effect of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competitive agreements deprive consumers and other drug purchasers such as Plaintiff and the Class of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

53. Agreements not to compete with an authorized generic can take many forms. According to the FTC Study, one such form includes agreements whereby the brand manufacturer agrees to exclusively supply the first-filing generic with the authorized generic product. The result is no competition between an authorized generic and the first-filing generic's product for a period of time.

FACTUAL ALLEGATIONS

A. Boehringer Starts Marketing Aggrenox in December 1999

54. Boehringer developed Aggrenox as a treatment to lower the risk of stroke in people who have had a transient ischemic attack (also known as a 'mini stroke') or stroke due to a blood clot. A transient ischemic attack is similar to a stroke, except it usually lasts only a few minutes and does not result in permanent damage. Aggrenox is a single gelatin capsule containing 200mg of extended-release dipyridamole and 25mg of immediate-release acetylsalicylic acid (aspirin). Boehringer has previously marketed dipyridamole as a stand-alone drug under the brand name Persantine to prevent clots from forming after heart valve replacements and aspirin has previously been prescribed for the prevention of strokes.

55. Boehringer filed NDA 020884 for Aggrenox and on November 22, 1999 received FDA approval to market Aggrenox to help reduce the risk of repeat strokes. Boehringer submitted Patent No. 6,015,577 (the '577 Patent) to the FDA for listing in the Orange Book. This patent was for a composition of dipyridamole and acetylsalicylic acid for oral administration. The '577 Patent is scheduled to expire on January 18, 2017.

56. Boehringer began marketing Aggrenox in December 1999. Aggrenox was the only prescription drug for reducing the risk of subsequent stroke through a single aspirin and extended-release dipyridamole capsule. Studies submitted to the FDA by Boehringer showed that Aggrenox's combined dipyridamole-aspirin formulation is more effective at reducing the risk of future stroke than administration of either ingredient on its own.

57. Aggrenox quickly became a commercial success and a steady source of profits for Boehringer. By 2008 Aggrenox sales in the United States had reached \$366 million.

B. Barr Seeks FDA Approval to Market a Generic Equivalent to Aggrenox

58. On January 31, 2007, Barr submitted ANDA 78-804 to the FDA, seeking approval to market a generic equivalent of Aggrenox. It submitted amendments to its ANDA on May 30, August 10, and November 14, 2007; June 6, August 25, and August 26, 2008; and July 1, July 13, July 14, and July 20, 2009. Barr was the first manufacturer to submit a substantially complete ANDA for generic Aggrenox with a Paragraph IV certification for the '577 Patent.

59. On May 31, 2007, Barr notified Boehringer that it had submitted ANDA 78-804 and a Paragraph IV certification regarding the '577 Patent, asserting that its generic would not infringe the patents and/or that the patents were invalid or unenforceable.

60. On July 11, 2007, Boehringer sued Barr for patent infringement in the United States Court for the District of Delaware. Boehringer's lawsuit triggered the 30-month stay that prohibited the FDA from granting final approval of Barr's ANDA.

61. Barr denied the allegations in Boehringer's complaint, and counterclaimed for declaratory relief of non-infringement, invalidity, and unenforceability of the '577 Patent. Barr argued that Boehringer had misrepresented to the USPTO the nature and materiality of a prior patent – Patent No. 5,694,024 – and its related reference DE-A1-3,515,874. According to Barr, the properly disclosed patent and reference would have made the claims of the '577 Patent obvious. In light of these allegations, Barr asked the District Court to find the '577 Patent unenforceable.

62. The patent lawsuit continued until August 2008 without any substantive rulings.

C. Boehringer and Barr Enter Into the Exclusion Payment Agreement

63. On August 11, 2008 Boehringer and Barr announced that they had settled the patent litigation. On August 13, Boehringer and Barr filed a stipulation seeking dismissal of the patent litigation with prejudice in light of the settlement. The Court entered the stipulation and dismissed the case the next day.

64. Under the terms of the settlement, Boehringer and Barr agreed that Barr would delay launching a generic equivalent of Aggrenox until at least July 1, 2015. The agreement unlawfully maintained Boehringer's exclusive right to sell Aggrenox, and Boehringer and Barr shared the revenue Boehringer derived as a result of its exclusivity (the "Exclusion Payment Agreement").

65. The Exclusion Payment Agreement between Boehringer and Barr had several components:

- a. **Settlement Agreement.** Boehringer and Barr agreed to dismiss all claims and counterclaims in the patent litigation and Barr agreed to delay launching a generic

version of Aggrenox until July 1, 2015. By granting Barr a license to market an authorized generic version of Aggrenox under Boehringer's NDA, Boehringer agreed not to compete against Barr with Boehringer's own authorized generic Aggrenox product. Absent the agreement, Boehringer had the incentive and ability to launch an authorized generic version of Aggrenox. The intended result of the agreement was that Barr would have de facto 180-day exclusivity for generic Aggrenox regardless of whether it was statutorily entitled to such exclusivity, and that there would be no competition between Barr's product and Boehringer's authorized generic product during the 180 days of exclusivity and beyond. This aspect of the agreement provides substantial compensation to Barr, which can expect to make approximately double the unit sales, at a much higher price, absent an authorized generic in the market. These higher prices come at the expense of Plaintiff and the End-Payor Class.

b. **Co-Promotion Agreement.** Boehringer agreed to pay Barr (through its subsidiary Duramed, now known as Teva Women's Health) for co-promotion services related to Aggrenox. Boehringer would train the existing 93-person Duramed Specialty Sales Force, who would promote Aggrenox to obstetricians, gynecologists, and women's health care professionals in exchange for a one-time fee plus annual, increasing royalties on the total U.S. Aggrenox sales for a period of seven years. The total value of these payments is an estimated \$120 million.

66. Boehringer's payments to Barr under the Exclusion Payment Agreement were given in exchange for Barr's agreement to delay the entry date of its generic product. Through the Federal Trade Commission ("FTC") subsequent investigation regarding the agency's investigation of Boehringer and Barr's agreements, Boehringer's counsel admitted that the Co-Promotion Agreement was the means by which Boehringer paid Barr to drop its patent challenge and stay out of the market.

He described it as “part and parcel of the settlement. It was part of the flow of compensation. It was part of the considerations of the settlement, so it is really a mischaracterization or misdescription to say that we said it was stand alone.” At other points, Boehringer’s counsel explained:

- The Settlement Agreement and Co-Promotion Agreement “were executed together. The evidence is replete that [the co-promotion agreement was] part of the settlement.”
- “We have always said that the Aggrenox co-promote was part of the settlement. It had – It absolutely was.”

67. The Co-Promotion Agreement was not a stand-alone business transaction, as evidenced by the fact that Boehringer’s payments under the co-promotion agreement vastly exceed the value of the services provided by Barr and its subsidiaries.

68. According to Boehringer’s own counsel, documents related to the Co-Promotion Agreement “provide a blueprint for how a company can extract settlement payments out of not only our client, but virtually every branded pharmaceutical company.”

D. Teva Acquired Barr and Continues the Unlawful Agreement to Suppress Generic Competition

69. On December 23, 2008, Teva acquired Barr and stepped into Barr’s shoes with respect to the Exclusion Payment Agreement. Teva has continued to refrain from entering the market with a generic equivalent of Aggrenox. Teva thus joined the ongoing unlawful course of conduct—and joined the unlawful agreements, collusion and conspiracy—to suppress generic competition of Aggrenox. Teva did not withdraw from the conspiracy, and instead continued to participate in it.

70. As a result of its acquisition of Barr, Teva would own (either directly or indirectly) ANDA 78-804 and the 180-day exclusivity period that Barr may be entitled to as the first filer.

71. Post-acquisition, Teva/Barr continued to pursue approval of ANDA 78-804. On August 14, 2009 the FDA granted final approval of ANA 78-804 for a generic equivalent of Aggrenox, and noted that Teva/Barr may have forfeited its 180-day exclusivity for failing to receive tentative approval within the requisite 30 months. Because of the Exclusion Payment Agreement, no generic equivalent of Aggrenox is on the market, and none will be on the market until July 1, 2015.

E. The Unlawful Agreement to Suppress Generic Competition Is Ongoing and Continues to Cause Harm

72. As for the filing of this complaint, no generic equivalent of Aggrenox is available in the United States. Another generic manufacturer has filed an ANDA for generic Aggrenox that includes a Paragraph IV certification for the '577 Patent. However, it is unlikely that any generic Aggrenox product will enter the market prior to July 2015. If Teva is found eligible for 180 days of marketing exclusivity and launches a generic equivalent of Aggrenox on July 1, 2015, the earliest another company can introduce a generic equivalent of Aggrenox is December 2015.

73. The lack of generic competition is the direct result of the ongoing unlawful agreement that began in 2008, has continued since then, and will continue at least through July 1, 2015. Boehringer continues to sell brand name Aggrenox at artificially inflated prices, and plaintiff has been denied the lower prices that generic competition would have brought to the market.

74. During the four-year period prior to the filing of this complaint, the defendants' unlawful conduct was ongoing and plaintiff and class members were injured every day that the defendants' unlawful agreement was in place.

75. But for the anticompetitive, illegal, and ongoing conduct alleged in this complaint, plaintiff and class members would have had access to less expensive versions of Aggrenox much sooner than they currently will. The defendants have injured plaintiff and class members by causing

them to pay substantial overcharges – potentially hundreds of millions of dollars – on their purchases of Aggrenox.

76. On January 15, 2009, the FTC issued a Resolution Authorizing Use of Compulsory Process in the Nonpublic Investigation to determine “whether Boehringer Ingelheim Pharmaceuticals, Inc. and Barr Pharmaceuticals, Inc., and their affiliates, or any other person, has engaged or is engaging in unfair methods of competition. . . with respect to the sale of Aggrenox or its generic equivalents and Mirapex and its generic equivalents.” FTC File No. 091-0023; *see Federal Trade Commission v. Boehringer Ingelheim Pharmaceuticals, Inc.*, Case No. 1:09-mc-00564-JMF, Dkt. # 1-1, at 3 (D.C.). As the FTC explained, “[c]ompensation rarely takes the form of explicit cash payments; instead, the settling firms typically include the payment in a separate business deal executed simultaneously with the settlement.” Case No. 12-5393 (D.C. Cir.), Brief of Appellant Federal Trade Commission, Doc. #1444255, p.9 (“FTC Brief”).

77. Pursuant to Sections 3 and 9 of the FTC Act, 15 U.S.C. §§ 43 and 49, on February 5, 2009 the FTC issued a subpoena to Boehringer seeking 37 categories of documents, including documents related to the settlement of the patent litigation, as well as the Exclusion Payment Agreement and the Co-Promotion Agreement. The FTC subpoena seeks – and Boehringer has so far refused to provide – its internal financial analysis regarding whether the payments Boehringer made to Barr under the Co-Promotion Agreement were for promotional services alone, or “side-payments for an anticompetitive agreement to delay generic entry and share the ensuing monopoly profits?” FTC Brief, at p.2. Boehringer has not produced any documents that would substantiate its assertion that the Co-Promotion Agreement provided Boehringer with substantial value distinct and apart from the benefits it derived from delaying generic competition for Aggrenox.

78. In light of Boehringer's refusal to turn over the relevant documents in response to the FTC's subpoena, on October 23, 2009 the FTC filed a petition with the District Court for the District of Columbia to enforce the subpoena. The FTC's petition did not specify the size of the payments from Boehringer to Barr under the Co-Promotion Agreement, and no other document filed publicly on the District Court docket contained this information.

79. On December 12, 2012, after the District Court had determined the Boehringer's internal financial analyses regarding the Co-Promotion Agreement were privileged and in large part denied the FTC's petition, the agency filed a Notice of Appeal with the Court of Appeals for the District of Columbia.

80. While Boehringer has not provided the FTC with its internal financial analyses, the FTC is in possession of the terms of the Co-Promotion Agreement. Based on this information, the FTC described the payments under the Co-Promotion Agreement as a "significant financial transaction." *Id.*, p. 36, n. 12. In a June 28, 2013 brief before the circuit court, the FTC explained that:

Under the agreement, Boehringer agreed to pay Barr a one-time fee plus annual, increasing royalties on the total U.S. Aggrenox sales for a period of years. . . . In 2008, Aggrenox had total U.S. sales of about \$366 million. . . . At this level of sales, the FTC estimates that the deal would ultimately cost Boehringer over \$120 million in royalties.

Id. The FTC's investigation is ongoing.

MARKET CHACTERISTICS

81. At all relevant times, Boehringer has had the power to maintain the price of Aggrenox at monopolistic levels without losing substantial sales to other products.

82. Aggrenox does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic equivalent Aggrenox.

83. Because of its unique profile as a combined aspirin and extended-release dipyridamole treatment for subsequent strokes, Aggrenox is differentiated from all products other than AB-rated generic equivalents of Aggrenox. Aggrenox's specific ratio of dipyridamole to aspirin and the release formulations of those components also differentiate it from products aside from AB-rated generic equivalents.

84. Boehringer needed to control only Aggrenox (and any AB-rated generic equivalents to Aggrenox), and no other products, to maintain the price of Aggrenox profitability at monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Aggrenox would render Boehringer unable to profitably maintain monopolistic prices of Aggrenox without losing substantial sales.

85. Boehringer also sold branded Aggrenox at prices well in excess of marginal costs and the competitive price, and enjoyed high profit margins.

86. The defendants have had and continue to exercise the power to exclude generic competition to branded Aggrenox.

87. At all relevant times, the defendants enjoyed high barriers to entry with respect to the market for Aggrenox products.

88. To the extent that plaintiff is legally required to define a relevant product market; plaintiff alleges that the relevant market is all Aggrenox products, which includes Aggrenox and AB-rated bioequivalent products. During the relevant time period, the defendants have been able to profitably maintain the price of Aggrenox well above competitive levels.

89. The relevant geographic market is the United States and its territories.

90. At all relevant times, Boehringer has had a 100% market share in the relevant market, and will continue to have that market share until July 2015.

MARKET EFFECTS

91. Boehringer began marketing Aggrenox in December 1999. No generic equivalent of Aggrenox has ever been available for purchase in the United States.

92. The defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Aggrenox from generic competition. But for the unlawful Exclusion Payment Agreement: (a) Barr would have entered the market upon receiving final FDA approval or agreed to an unrestrained licensed entry date much earlier than July 1, 2015; and (b) Boehringer would have launched an authorized generic version of Aggrenox simultaneously with the launch of Barr's generic Aggrenox product.

93. But for the defendants' illegal conduct, generic competition would have forced a decrease in the price of branded Aggrenox, and price competition among the suppliers of branded and generic Aggrenox would have been intense.

94. But for the defendants' illegal conduct, plaintiff and class members would have paid less for Aggrenox or a generic equivalent. The defendants' conduct directly injured plaintiff and class members because if forced them to pay hundreds of millions of dollars in overcharges on their Aggrenox purchases.

95. As a result of the delay in generic competition brought about by the defendants' anticompetitive scheme, plaintiff and class members paid more for Aggrenox products than they would have paid absent the defendants' illegal conduct.

96. Barr had extensive experience in the pharmaceutical industry, including experience obtaining approval of ANDAs, manufacturing commercial launch quantities adequate to meet market demand, and marketing generic pharmaceutical products.

97. Upon entering the market, generic equivalents of brand name drugs are priced significantly below the branded drug to which they are AB-rated. When multiple generic products are on the market, prices for the brand drug and its generic equivalents fall even further because of the increased competition.

98. If generic competition for Aggrenox had not been unlawfully delayed, end-payors would have paid less for Aggrenox by (a) substituting purchases of less-expensive AB-rated generic equivalents of Aggrenox for their purchases of more-expensive brand Aggrenox, and (b) purchasing brand name Aggrenox at a reduced price.

99. Thus, the defendants' unlawful conduct deprived plaintiff of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT

100. During the relevant period, plaintiff and class members purchased substantial amounts of Aggrenox indirectly from Boehringer. As a result of the defendants' illegal conduct, these purchasers were compelled to pay artificially inflated prices for Aggrenox. Those prices were substantially higher than the prices that plaintiff and class members would have paid absent the illegal conduct alleged in this complaint.

101. As a consequence, purchasers of Aggrenox have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

102. Defendants' efforts to restrain competition in the market for Aggrenox have substantially affected interstate and foreign commerce.

103. At all material times, Boehringer manufactured, promoted, distributed, and sold substantial amounts of Aggrenox in a continuous and uninterrupted flow of commerce across state

and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic equivalents of Aggrenox to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

104. At all material time, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Aggrenox.

105. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. See Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* (1994) at 624. Professor Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top. He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

106. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Aggrenox to plaintiff and class members.

107. Defendants' anticompetitive conduct enabled Boehringer to indirectly charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the defendants' unlawful actions.

108. The prices were inflated as a direct and foreseeable result of defendants' anticompetitive conduct.

109. The inflated prices that plaintiff and class members have paid are traceable to, and the foreseeable result of, the overcharges by Boehringer.

CLASS ACTION ALLEGATIONS

110. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of a Class defined as follows:

All persons or entities who indirectly purchased and/or paid for some or all of the purchase price for Aggrenox, in any form, in the United States and the District of Columbia and Puerto Rico, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the “Class” or the “End-Payor Class”), other than for resale, during the period November 2009 through and until the anticompetitive effects of Defendants’ unlawful conduct cease (the “Class Period”). For purposes of the Class definition, persons or entities “purchased” Aggrenox if they paid or reimbursed some or all of the purchase price.

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

111. Members of the Class are so numerous and geographically dispersed that joinder is impractical. Further, the Class is readily identifiable from information and records in the possession of the Defendants.

112. Plaintiff’s claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for Aggrenox and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Aggrenox as a result of Defendants’ wrongful conduct.

113. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

114. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

115. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate.

116. Questions of law and fact common to the Class include, but are not limited to:

- a. whether Defendants conspired to willfully maintain and/or enhance Boehringer's monopoly power over Aggrenox;
- b. whether Defendants conspired to suppress generic competition to Aggrenox;
- c. whether Defendants entered into an unlawful agreement in restraint of trade;
- d. whether, pursuant to the Agreements, the Generic Defendants agreed to delay their entry into the market with generic Aggrenox;
- e. whether, pursuant to the Agreements, Boehringer compensated the Generic Defendants;
- f. whether Boehringer's compensation to the Generic Defendants was for any purpose other than delayed entry of generic Aggrenox;
- g. whether Boehringer's compensation to the Generic Defendants was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;
- h. whether the Agreements created a bottleneck to generic competition;
- i. whether one or more of the Agreements is illegal;
- j. whether Boehringer possessed substantial market power over Aggrenox;

- k. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;
- l. whether Boehringer maintained monopoly power over Aggrenox by unlawfully suppressing generic competition to Aggrenox;
- m. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- n. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Class; and
- o. the quantum of aggregate overcharge damages to the Class.

117. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without necessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method of obtaining redress on claims that could not practically be pursued individually, substantially outweighs potential difficulties in management of this class action.

118. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

FRAUDULENT CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

119. Plaintiff and class members had no knowledge of the defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years prior to the filing of this complaint.

120. This is true because the nature of defendants' conspiracy was self-concealing and because the defendants employed deceptive practices and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme. Notwithstanding the self-concealing nature of their conspiracy, defendants and their co-conspirators wrongfully and affirmatively concealed the existence of their continuing combination and conspiracy from plaintiff and class members by, among other things:

- a. Concealing the amounts that Boehringer was to pay and paid Barr/Teva under the Exclusion Payment Agreement;
- b. Concealing the fact that the purpose of the payments under the Co-Promotion Agreement was to provide compensation to Barr/Teva in connection with the settlement of the '577 Patent litigation and the entry date for Barr/Teva's generic product;
- c. Concealing the fact that those amounts far exceeded any lawful economic benefit that Boehringer received from Barr/Teva under the agreement; and
- d. Filing documents with the SEC that failed to disclose the existence or nature of the Exclusion Payment Agreement. Teva's fiscal year 2008 20-F did not mention the settlement of the Aggrenox litigation. The 20-F also mentioned a co-promotion agreement for a different pharmaceutical product, but did not mention the Aggrenox Co-Promotion Agreement. Teva's 20-F filings for the fiscal years

2009, 2010, 2011, and 2012 similarly failed to disclose the Aggrenox settlement or the Co-Promotion Agreement.

121. Because the alleged conspiracy was both self-concealing and affirmatively concealed by defendants and their co-conspirators, plaintiff and class members had no knowledge of the conspiracy more than four years prior to the filing of this complaint, or of the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

122. Plaintiff and class members also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred, including the amounts of payments made from Boehringer to Barr/Teva under the Co-Promotion Agreement. Reasonable diligence on the part of Plaintiff and class members would not have uncovered those facts more than four years prior to the filing of this complaint.

123. As a result of defendants' fraudulent concealment, all applicable statutes of limitations affecting plaintiff's and class members' claims have been tolled.

124. Alternatively, if the statute of limitations is not tolled, this complaint alleges a continuing course of conduct (including conduct within the limitations period), and plaintiff and class members can recover damages they suffered during the limitations period.

CLAIMS FOR RELIEF

COUNT I

CLAIM FOR INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATION OF SECTIONS 1 AND 2 OF THE SHERMAN ACT

125. Plaintiff incorporates by reference the preceding allegations and paragraphs.

126. Plaintiff brings this case under Section 16 of the Clayton Act (15 U.S.C. § 26) on behalf of itself and the Class.

127. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to block and delay entry of competing Aggrenox formulations, i.e., AB-rated generic versions of Aggrenox. The intended and accomplished goal of the scheme was to maintain Boehringer's monopoly power using restrictive and exclusionary conduct to delay FDA approval of ANDAs for generic Aggrenox products. Defendants injured Plaintiff and the Class through, inter alia, and agreements to exclude generic Aggrenox product from the market in exchange for cash payments and royalties on the brand Aggrenox product.

128. Boehringer repeatedly asserted that the generic Aggrenox formulations of its competitors infringed its patents, despite knowing that the Aggrenox patents were invalid and/or unenforceable.

129. It was the Defendants' conscious objective to further Boehringer's monopoly in the relevant market through the overarching anticompetitive scheme. Defendants conspire to monopolize, and did wrongfully and intentionally maintain monopoly power, with respect to Aggrenox in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices.

130. Had manufacturers of generic Aggrenox products entered the market and lawfully competed with Boehringer in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic Aggrenox products for the higher-priced brand-name Aggrenox for some or all of their Aggrenox product requirements, and/or would have paid lower net prices on their remaining Aggrenox and/or AB-rated bioequivalent purchases.

131. Defendants intended, and accomplished, a horizontal market allocation of the Aggrenox market, a *per se* violation of Section 1 of the Sherman Act. By their Agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of

trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiff and members of the Class paid artificially inflated prices for their Aggrenox requirements.

132. Plaintiff and members of the Class purchased substantial amounts of Aggrenox indirectly from Boehringer and/or other manufacturers.

133. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

134. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

COUNT II

CLAIM FOR MONOPOLIZATION UNDER STATE LAW

135. Plaintiff incorporates by reference the preceding allegations and paragraphs.

136. This claim is pled as to Boehringer only.

137. At all relevant times, Boehringer possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Boehringer possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

138. Through the overarching anticompetitive scheme, as alleged extensively above, Boehringer willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for its monopolized Aggrenox product.

139. The goal, purpose and effect of Boehringer's scheme was to prevent and delay the sale of Aggrenox products in the United States at prices substantially below Boehringer's prices for Aggrenox, thereby effectively preventing the average market price of Aggrenox products from declining dramatically.

140. By engaging in the foregoing conduct, Boehringer has violated the following states' antitrust and/or unfair and deceptive trade practices acts of:

- a) Arizona: The aforementioned practices by the Defendant were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. § 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat. § 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;
- b) California: The aforementioned practices by the Defendant were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code § 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, *et seq.*;
- c) District of Columbia: The aforementioned practices by the Defendant were and are in violation of the District of Columbia Antitrust Act, D.C. Code §28-4501, *et seq.*;
- d) Florida: The aforementioned practices by the Defendant were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §501.201, *et seq.*;
- e) Illinois: The aforementioned practices by the Defendant were and are in violation of 740 Ill. Comp. Stat. 10/7(2);

- f) Iowa: The aforementioned practices by the Defendant were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);
- g) Kansas: The aforementioned practices by the Defendant were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §50-101, *et seq.*;
- h) Massachusetts: The aforementioned practices by the Defendant were and are in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch 93A, § 11;
- i) Maine: The aforementioned practices by the Defendant were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. Tit. 10, § 1101, *et seq.*;
- j) Michigan: The aforementioned practices by the Defendant were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.771, *et seq.*, and the Michigan Consumer Protection Act, § 445.901, *et seq.*;
- k) Minnesota: The aforementioned practices by the Defendant were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. § 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat § 325F.67, *et seq.*;
- l) Mississippi: The aforementioned practices by the Defendant were and are in violation of Miss. Code Ann. § 75-21-1, *et seq.*;
- m) Missouri: The aforementioned practices by the Defendant were and are in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.025;
- n) Nebraska: The aforementioned practices by the Defendant were and are in violation of Ne. Rev. Stat. § 59-801, *et seq.*;

- o) Nevada: The aforementioned practices by the Defendant were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. § 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 598.0903, *et seq.*;
- p) New Mexico: The aforementioned practices by the Defendant were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq.*;
- q) New York: The aforementioned practices by the Defendant were and are in violation of N.Y. Gen. Bus. Law § 340, *et seq.*, and, N.Y. Gen. Bus. Law § 349, *et seq.*;
- r) North Carolina: The aforementioned practices by the Defendant were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. § 75-1, *et seq.*;
- s) North Dakota: The aforementioned practices by the Defendant were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code § 51-08.1-01, *et seq.*;
- t) Pennsylvania: The aforementioned practices by the Defendant were and are in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et seq.*;
- u) Puerto Rico: The aforementioned practices by the Defendant were and are in violation of the Puerto Rico Antitrust Act, Puerto Rico Code 10 LPRA § 257, *et seq.*;

- v) South Dakota: The aforementioned practices by the Defendant were and are in violation of South Dakota's antitrust law, S.D. Codified Laws § 37-1-3, *et seq.*;
- w) Tennessee: The aforementioned practices by the Defendant were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. § 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq.*;
- x) Vermont: The aforementioned practices by the Defendant were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;
- y) West Virginia: The aforementioned practices by the Defendant were and are in violation of the West Virginia Antitrust Act, W. Va. Code § 47-18-1.
- z) Wisconsin: The aforementioned practices by the Defendant were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. § 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. § 100.20, *et seq.*

339. Plaintiff and members of the Class have been injured in their business or property by reason of Defendant's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Aggrenox, sooner, and (2) paying higher prices for Aggrenox than they would have paid in the absence of Defendant's conduct. These injuries are the type the antitrust laws were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

340. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendant's violations of the aforementioned statutes.

COUNT III

AGREEMENT IN RESTRAINT OF TRADE

341. Plaintiff incorporate by reference the preceding allegations and paragraphs.

342. This claim is pled as to all Defendants.

343. On or before November 2009, Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the Aggrenox/generic equivalent market through the present by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

344. The Agreement between Boehringer and the Generic Defendants to monopolize the Aggrenox market includes overt acts between separate economic entities—actual and potential competitors—and is illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that the agreement and conspiracy to monopolize is a violation of state antitrust law under a “quick look” or “rule of reason” analysis.

346. Boehringer and the Generic Defendants knowingly and intentionally conspired to maintain and enhance Boehringer’s monopoly power in the relevant market. Boehringer and the Generic Defendants specifically intended that the overarching anticompetitive scheme would maintain

347. Boehringer’s monopoly power in the relevant market the injured Plaintiff and the Class thereby.

348. Boehringer and the Generic Defendants each committed at least one over act in furtherance of the conspiracy.

349. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the following state statutes:

- a) Arizona: The aforementioned practices by the Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. § 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat. § 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;
- b) California: The aforementioned practices by the Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code § 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, *et seq.*;
- c) District of Columbia: The aforementioned practices by the Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §28-4501, *et seq.*;
- d) Florida: The aforementioned practices by the Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §501.201, *et seq.*;
- e) Illinois: The aforementioned practices by the Defendants were and are in violation of 740 Ill. Comp. Stat. 10/7(2);
- f) Iowa: The aforementioned practices by the Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

- g) Kansas: The aforementioned practices by the Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §50-101, *et seq.*;
- h) Massachusetts: The aforementioned practices by the Defendants were and are in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch 93A, § 11;
- i) Maine: The aforementioned practices by the Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. Tit. 10, § 1101, *et seq.*;
- j) Michigan: The aforementioned practices by the Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.771, *et seq.*, and the Michigan Consumer Protection Act, § 445.901, *et seq.*;
- k) Minnesota: The aforementioned practices by the Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. § 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat § 325F.67, *et seq.*;
- l) Mississippi: The aforementioned practices by the Defendants were and are in violation of Miss. Code Ann. § 75-21-1, *et seq.*;
- m) Missouri: The aforementioned practices by the Defendants were and are in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.025;
- n) Nebraska: The aforementioned practices by the Defendants were and are in violation of Ne. Rev. Stat. § 59-801, *et seq.*;
- o) Nevada: The aforementioned practices by the Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. § 598A.010,

- et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 598.0903, *et seq.*;
- p) New Mexico: The aforementioned practices by the Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq.*;
 - q) New York: The aforementioned practices by the Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law § 340, *et seq.*, and the New York Deceptive Act and Practices Act, N.Y. Gen. Bus. Law § 349, *et seq.*;
 - r) North Carolina: The aforementioned practices by the Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. § 75-1, *et seq.*;
 - s) North Dakota: The aforementioned practices by the Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code § 51-08.1-01, *et seq.*;
 - t) Pennsylvania: The aforementioned practices by the Defendants were and are in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et seq.*;
 - u) Puerto Rico: The aforementioned practices by the Defendants were and are in violation of Puerto Rico Antitrust Act, Puerto Rico Code 10 LPRA § 257, *et seq.*;
 - v) South Dakota: The aforementioned practices by the Defendant were and are in violation of South Dakota's antitrust law, S.D. Codified Laws § 37-1-3, *et seq.*;

- w) Tennessee: The aforementioned practices by the Defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. § 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq.*;
- x) Vermont: The aforementioned practices by the Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;
- y) West Virginia: The aforementioned practices by the Defendants were and are in violation of the West Virginia Antitrust Act, W. Va. Code § 47-18-1.
- z) Wisconsin: The aforementioned practices by the Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. § 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. § 100.20, *et seq.*

350. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Aggrenox, sooner, and (2) paying higher prices for Aggrenox than they would have paid in the absence of Defendants' conduct. These injuries are the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

351. Plaintiff and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

COUNT IV

UNJUST ENRICHMENT AND DISGORGEMENT OF PROFITS

352. Plaintiff incorporates by reference the preceding allegations and paragraphs.

353. Defendants have benefited from the monopoly profits on their sales of Aggrenox and/or AB-rated bioequivalents resulting from the unlawful and inequitable acts alleged in this Complaint.

354. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Aggrenox and AB-rated bioequivalents by Plaintiff and members of the Class.

355. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

356. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they had a privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiff and the Class.

357. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Aggrenox, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Defendants.

358. The economic benefit of overcharges and unlawful monopoly profits derived by the Defendants through charging supracompetitive and artificially inflated prices for Aggrenox are a direct and proximate result of Defendants' unlawful practices.

359. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

360. It would be inequitable under the laws of all states and jurisdictions within the United States for the Defendants to be permitted to retain any of the overcharges for Aggrenox and/or AB-rated bioequivalents derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

361. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds received by them.

362. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

363. Plaintiff and the Class have no adequate remedy at law.

JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Class, demand a trial by jury on all issues so triable.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the End-Payor Class, demand judgment for the following relief:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff representative of the End-Payor Class.
- B. Declare that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment under the laws of all states and jurisdictions within the United States;

- C. Enjoin Defendants from continuing the illegal activities alleged herein;
- D. Enter joint and several judgments against Defendants in favor of Plaintiff and the End-Payor Class;
- E. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
- F. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;
- G. Award Plaintiff and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided for by law; and
- H. Grant such other further relief as is necessary to correct for the anticompetitive market effort caused by the unlawful conduct of Defendants, and as the Court deems just, equitable and proper.

Date: November 18, 2013

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